LEGISLATIVE SERVICES AGENCY OFFICE OF FISCAL AND MANAGEMENT ANALYSIS

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FISCAL IMPACT STATEMENT

LS 7359 NOTE PREPARED: Jan 13, 2013

BILL NUMBER: HB 1315 BILL AMENDED:

SUBJECT: Biosimilar Biological Products.

FIRST AUTHOR: Rep. Clere BILL STATUS: As Introduced

FIRST SPONSOR:

FUNDS AFFECTED: X GENERAL IMPACT: State

DEDICATED FEDERAL

<u>Summary of Legislation:</u> This bill provides that a biological product that is substituted under the biosimilar biological products requirements is not subject to the generic drug substitution requirements. The bill allows a pharmacist to substitute a biosimilar product for a prescribed biological product if certain conditions are met.

The bill requires the Board of Pharmacy to maintain a web site that lists the biosimilar biological products that are determined to be interchangeable.

The bill allows the Board of Pharmacy to adopt rules. It also provides for disciplinary action for violations by a pharmacist.

Effective Date: July 1, 2013.

Explanation of State Expenditures: The Indiana Professional Licensing Agency (IPLA) reports that the Board of Pharmacy Internet web page requirement can be accomplished within the level of resources currently available to the agency.

Explanation of State Revenues:

Explanation of Local Expenditures:

Explanation of Local Revenues:

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State Agencies Affected: IPLA, Board of Pharmacy.

Local Agencies Affected:

Information Sources: IPLA.

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